IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC and BESINS HEALTHCARE INC.,)
Plaintiffs,)
v.) C.A. No. 13-236 (RGA)
PERRIGO COMPANY and PERRIGO ISRAEL PHARMACEUTICALS LTD.,)
Defendants.)) _)
UNIMED PHARMACEUTICALS, LLC and BESINS HEALTHCARE INC.,)
Plaintiffs,)
v.) C.A. No. 13-496 (RGA)
WATSON LABORATORIES, INC. and ACTAVIS, INC.,)
Defendants.)

SCHEDULING ORDER

This day of September, 2013, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. <u>Consolidation</u>. In light of the overlapping issues involved and for the convenience of the Court, case numbers C.A. 13-236 (RGA) and 13-496(RGA) are consolidated

for all purposes. All filings in both cases will be captioned as above and made under C.A. 13-236.

- 2. <u>Bifurcation of Certain Issues</u>. This matter will be bifurcated, such that all proceedings, including discovery, relating solely to Perrigo's counterclaim alleging patent misuse or solely to any claim by any party for an exceptional case finding under 35 U.S.C. § 285 will be stayed until after a final decision on appeal has been entered on the merits of the remaining issues. This Scheduling Order relates only to the first phase of the litigation; if necessary, a schedule relating to the patent misuse and § 285 claims will be entered at a later date.
- Products/Patents. The parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) on or before September 30, 2013. As part of the Rule 26(a)(1) initial disclosures, defendants will produce to plaintiffs full electronic copies of their respective Abbreviated New Drug Applications (ANDAs). Plaintiffs will accept the ANDAs on an attorneys' eyes only basis, pending entry of a Protective Order in this matter. On or before

This does not include the "Initial Disclosures" described in paragraph 3 of the *Default Standard for Discovery, Including Discovery of Electronically Stored Information* ("Default Standard"). The paragraph 3 disclosures will be made not later than 45 days after the Rule 16 conference.

Any attorneys accessing the ANDA shall not be involved in the prosecution or preparation of patent applications related to testosterone and formulations or methods of use thereof, or the preparation or prosecution of any filings with the FDA related to testosterone and formulations or methods of use thereof, pending entry of a Protective Order in this matter. The Protective Order will govern access to the ANDA once entered.

October 18, 2013, Plaintiffs will specifically identify Defendants' accused products and the patents they allegedly infringe, and will produce the file history for each asserted patent.³

4. <u>Joinder of Other Parties and Amendment of Pleadings</u>. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before April 25, 2014.

5. Discovery.

- a. <u>Parties</u>: For purposes of serving and responding to discovery, and to give context to the limits set forth below, the parties shall be (1) Unimed Pharmaceuticals, LLC ("Unimed"); (2) Besins Healthcare Inc. ("Besins"); (3) Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (together, "Perrigo"); and (4) Watson Laboratories, Inc. and Actavis, Inc. (together, "Watson"). Plaintiffs agree that Defendants may obtain discovery from AbbVie as it if were a party to this litigation, without need to issue Rule 45 document or deposition subpoenas, though Plaintiffs and AbbVie reserve the right to object to any such discovery sought on other appropriate grounds.
- b. <u>Discovery Cut Off.</u> All fact discovery in this case shall be initiated so that it will be completed on or before August 15, 2014.
- c. <u>Document Production</u>. Document production shall be substantially complete by April 18, 2014.

The disclosures required by paragraph 4(b), (c) and (d) of the Default Standard will then follow on November 18, 2013; December 18, 2013; and February 14, 2014, respectively. In addition, the parties agree that "follow up discovery shall be limited to a term of 6 years before the filing of the complaint" provided for in paragraph 4(e) of the Default Standard shall not apply to this case, and the parties will work in good faith with respect to specific discovery requests regarding appropriate time limits.

- d. Requests for Admission. Plaintiffs jointly may serve no more than 100 Requests for Admission on each of Perrigo and Watson. Defendants may serve no more than 50 joint Requests for Admission on Plaintiffs collectively. In addition, Perrigo and Watson shall each be entitled to serve up to 50 individual Requests for Admission on Plaintiffs collectively. Requests for Admission directed solely to authentication of documents do not count toward these limits.
- e. <u>Interrogatories</u>. Plaintiffs jointly may serve no more than 25 interrogatories on each of Perrigo and Watson. Defendants may serve no more than 5 joint interrogatories on Plaintiffs collectively. In addition, Perrigo and Watson shall each be entitled to serve no more than 20 individual interrogatories on Plaintiffs collectively.

f. <u>Depositions</u>.

Limitation on Fact Depositions. Plaintiffs are limited to no more than 16 total fact depositions of Defendants, with no more than 9 depositions of Perrigo or Watson individually. Defendants are limited to no more than 18 total fact depositions of Plaintiffs, collectively, with Perrigo and Watson entitled to at least 9 depositions each. In addition, each side (Plaintiffs collectively and Defendants collectively) will be entitled to conduct up to six (6) depositions of third parties as fact witnesses, with Perrigo and Watson entitled to at least 3 depositions each. For purposes of this paragraph, the Parties will count depositions of persons named as an "inventor" on the face of a patent-in-suit, or alleged to be an "inventor" by Plaintiffs as well as depositions of AbbVie employees, as "party" depositions, and not depositions of "third parties," regardless whether such depositions take place pursuant to notice or subpoena. Depositions will be limited to seven (7) hours, but the parties will work together in good faith to adjust this presumptive limit if a party requests more time with a

particular witness. Each noticed Rule 30(b)(6) deposition shall be counted as one (1) deposition, regardless of the number of individual witnesses designated by the noticed party to testify as to the noticed topics, provided that the number of topics in any individual notice does not exceed eight (8). Nothing in this paragraph prevents one party from examining a witness during a deposition noticed by another party.

Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Since Perrigo has filed counterclaims, it shall be considered as having filed an action in this Court for the purpose of this provision. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. The parties hereby agree to allow depositions within the U.S., but outside this District, for the convenience of the witness(es); nothing in this paragraph precludes the parties from making further agreements concerning exceptions to this general rule.

g. <u>Discovery Matters and Disputes Relating to Protective Orders.</u>
Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than forty-eight hours prior to the conference/argument, the party seeking relief shall file with Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than twenty-four hours prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining the party's reasons for its opposition. Should any document(s) be filed

under seal, a courtesy copy of the sealed document(s) must be provided to the Court within one hour of e-filing the document(s).

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

- h. <u>Specific E-Discovery Issues</u>. E-Discovery issues are addressed in paragraph 5 of the Default Standard. The parties agree to continue to work in good faith with respect to the ESI issues addressed in paragraph 5 of the Default Standard and agree to submit to the Court a separate submission addressing same within twenty-one days (21) of the Rule 16 conference.
- 6. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within thirty days from the date of this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 3(g) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

- 7. <u>Papers Filed Under Seal</u>. When filing papers under seal, counsel shall deliver to the Clerk an original and one copy of the papers. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.
- 8. <u>Courtesy Copies</u>. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.
- 9. Claim Construction Issue Identification. On or before February 14, 2014, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe will likely be disputed and require construction. On or before March 7, 2014, the parties will exchange their proposed claim construction of those term(s)/phrase(s). These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than March 19, 2014. The parties' Joint Claim Construction Chart, in Word or WordPerfect format, shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

Claim Construction Briefing. The Plaintiffs shall serve, but not file, their opening brief, not to exceed 20 pages, on April 9, 2014. Defendants shall serve, but not file, their joint answering brief, not to exceed 30 pages, on May 7, 2014. An individual Defendant may address issues not common to all Defendants in an additional, short answering brief of no more than five (5) pages. Plaintiffs shall serve, but not file their reply brief, not to exceed 20 pages, on June 4, 2014. Plaintiffs reserve the right to seek leave to exceed this page limit in proportion to the number and length of any additional brief submitted by Defendants. Defendants shall serve, but not file, their joint sur-reply brief, not to exceed 10 pages, on June 18, 2014. No later than July 2, 2014, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

The parties dispute whether a Certificate of Correction issued December 16, 2003 in connection with U.S. Patent No. 6,503,894 ("the '894 patent"), is valid or invalid, at least as it relates to the purported amendment of the '894 patent to include the term "0.1 N" before the term "sodium hydroxide" in each of claims 1, 9, 10, and 18. To prevent the parties and the Court from addressing such issues more than once, and to otherwise promote judicial economy, the parties agree to postpone presentation to the Court of the dispute regarding whether the December 16, 2003 Certificate of Correction is valid or invalid until the infringement/invalidity portion of the case. For purposes of claim construction only, the parties agree that they will address in the Joint Claim Construction Chart, in the parties' respective claim construction briefs, or at the hearing on claim construction, any issue with the scope and meaning of claim terms themselves, considering the claim language that would be in force (1) if the Certificate of Correction is found valid, and (2) if the Certificate of Correction is found invalid.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Agreed-Upon Constructions
- II. Disputed Constructions

A. [TERM 1]

- 1. Plaintiff's Opening Position
- 2. Defendant's Answering Position
- 3. Plaintiff's Reply Position
- 4. Defendant's Sur-Reply Position

B. [TERM 2]

- 1. Plaintiff's Opening Position
- 2. Defendant's Answering Position
- 3. Plaintiff's Reply Position
- 4. Defendant's Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

11. <u>Hearing on Claim Construction</u>. Beginning at 8:30 a.m. on August 27, 2014, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours.

12. <u>Disclosure of Expert Testimony.</u>

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or

before October 17, 2014. Disclosure of expert testimony relating to Plaintiffs' asserted secondary considerations of non-obviousness is also due on or before October 17, 2014. Responsive expert reports are due on or before November 14, 2014. Reply expert reports are due on or before December 12, 2014. Depositions of experts shall be completed on or before February 7, 2015.

- b. <u>Objections to Expert Testimony</u>. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm.*, *Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than five weeks before the pretrial conference set by the Court, unless otherwise ordered by the Court.
- 13. <u>Applications by Motion</u>. Except as otherwise specified herein, any application to the Court shall be by written motion.
- 14. <u>Pretrial Conference</u>. On March 13, 2015, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 11:00 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the third business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.
- 15. <u>Motions in Limine</u>. Motions in limine shall not be separately filed. All in limine requests and responses thereto shall be set forth in the proposed pretrial order. Each party shall be limited to three in limine requests, unless otherwise permitted by the Court. The in limine request and any response shall contain the authorities relied upon; each in limine request may be supported by a maximum of three pages of argument and may be opposed by a maximum

of three pages of argument, and the party making the in limine request may add a maximum of

one additional page in reply in support of its request. If more than one party is supporting or

opposing an in limine request, such support or opposition shall be combined in a single three

page submission (and, if the moving party, a single one page reply). No separate briefing shall

be submitted on *in limine* requests, unless otherwise permitted by the Court.

16. <u>Trial</u>. This consolidated matter is scheduled for a 4-day bench trial

beginning at 9:30 a.m. on March 30, 2015, with the subsequent trial days beginning at a time

directed by the Court. The trial will be timed, as counsel will be allocated a total number of

hours in which to present their respective cases.

17. ADR Process. This matter is referred to a magistrate judge to explore the

possibility of alternative dispute resolution.

JNITED STATES DISTRICT JUDGE

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